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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/706,322 | 11/12/2003 | Enrique Carlos Leira | SLU 00-013 | 6487 |
| 33436 | 7590 | 11/16/2006 | EXAMINER | |
| SAINT LOUIS UNIVERSITY OFFICE OF INNOVATION AND INTELLECTUAL PROPERTY 3556 CAROLINE MALL SUITE C208 ST. LOUIS, MO 63104 | | | GRAY, PHILLIP A | |
| | | ART UNIT | | PAPER NUMBER |
| | | | | 3767 |
| DATE MAILED: 11/16/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/706,322 | LEIRA ET AL. |
| | Examiner | Art Unit |
| | Phillip Gray | 3767 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 12 November 2003.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-38 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-38 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/17/04</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

This office action is in response to applicant's communication of 11/12/2003.

Currently claims 1-38 are pending and rejected below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7,13,16-22,24, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by TEH (U.S. Patent Number 5,514,110). Teh discloses an automatic flow control device, method, and kit, which is used for collecting a fluid comprising a pressure sensitive valve (as in figure 3). The Teh device valve comprises a housing (7) and inlet (near 14), an outlet (near 15), a fluid channel (unnumbered area from 14 to 15, as in figure 3), and a cylinder shaped rod (9) which can obstruct the communication between the inlet and outlet such that when a pressure differential between the inlet and the outlet is at or greater than a preset value, the rod is displaced to obstruct the fluid from flowing from the inlet to the outlet and when the pressure differential between the inlet and the outlet is less than the preset value, the rod is not displaced to allow the fluid to flow from the inlet to the outlet, and valves (for instance 1,4,5,6). This rod is connected to the outlet by a spring (12) and retaining pin (8). Further the Teh rod is

perpendicular to the fluid channel (as the fluid enters opening 10), has a constriction opening 10 and space through rod near 16) and in a rod sleeve (material around element 8 in which rod 9 is moveable in). Further the rod is inline with the fluid channel (as the fluid flows through the inlet before entering opening 10 and as fluid flows from 16 to outlet 15). Further Teh teaches a rod comprising a rod channel (opening near 16) with is contiguous with the fluid channel.

Teh teaches that a needle is affixed to the inlet to the housing (see figure 11a element near 6 or 36) and that tubing (between 4 and 2) is affixed to the outlet from the housing (see figures 1, 2, or 11a for example).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-11, 12, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teh.

Concerning claims 8-11, Teh discloses the claimed invention except for the preset value is at or greater than 10 mm of H₂O, 50 mm of H₂O, 100mm of H₂O, or between 179mm and 221mm of H₂O. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a preset value is at or greater than 10 mm of H₂O, 50 mm of H₂O, 100mm of H₂O, or between 179mm and 221mm of H₂O, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) and it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (CCPA 1955).

Concerning claims 12 and 23, Teh discloses the claimed invention except for the fluid comprising body fluid, blood, or CSF. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the fluid be body fluid, blood, or CSF, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Claims 14,15,25,26, and 28-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teh in view of Bierman (U.S. Patent Number 2,535,998).

Teh discloses the claimed invention except for the stopcock, threeway valve, and manometer assembly is affixed to the outlet from the housing. Bierman teaches that it is known to use a stopcock, threeway valve, and manometer assembly is affixed to the outlet from the housing as set forth in paragraphs at columns 1-3 to provide an ability for the pulse to be observed and control fluid flow by stopping. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the flow control system as taught by Teh with the stopcock, threeway valve, and manometer assembly is affixed to the outlet from the housing as taught by Bierman, since such a modification would provide the flow control system with a stopcock, threeway valve, and manometer assembly is affixed to the outlet from the housing for providing an ability for the pulse to be observed and control fluid flow by stopping.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons